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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,315	12/30/2003	Andrew Berlin	070702007900	1701

7590 09/05/2006

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EXAMINER

CROW, ROBERT THOMAS

ART UNIT PAPER NUMBER

1634

DATE MAILED: 09/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/750,315

Applicant(s)

BERLIN ET AL.

Examiner

Robert T. Crow

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 14 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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FINAL ACTION

Status of the Claims

1. This action is in response to papers filed 14 June 2006 in which claims 18-23 were amended, no claims were canceled, and no claims were added. All of the amendments have been thoroughly reviewed and entered.
2. The previous rejections under 35 U.S.C. 112, second paragraph, are withdrawn in view of the amendments.
3. The previous rejections under 35 U.S.C. 102(b,e) and 35 U.S.C. 103(a) not reiterated below are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed and are addressed following the rejections necessitated by the amendments.
4. The previous rejections under the judicially created doctrine of obviousness-type double patenting are withdrawn in view of Applicant's filing of a Terminal Disclaimer, which was approved on 26 June 2006.
5. Claims 18-23 are under prosecution.

Support for Amendments to the Claims

It is noted that the support for the duplicate Raman detection units is found in paragraph [0038] of the Specification, and not in paragraph [0040] as cited on page 8 of the Remarks filed 14 June 2006.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 23 recites " a mesh inside the channel" in lines 1-2 of the claim. It is unclear if the mesh is inside the inlet channel or the outlet channel.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Davis (U.S. Patent Application Publication No. US 2002/0102595, published 1 August 2002).

Regarding claim 18, Davis teaches an apparatus (e.g., a system for optical detection; claim 15) comprising:

a reaction chamber containing a single template nucleic acid molecule attached to an immobilization surface (e.g., an immobilized primer complex; paragraph 0005 and feature #2 of Figure 1, wherein the chamber is defined as the region of the flow stream of the flow cell; Figure 1 and paragraph 0006);

an inlet channel in fluid communication with the reaction chamber (Figure 1 and paragraph 0006, wherein the inlet channel is defined as the region of the flow cell upstream from the region having the immobilized primer complex; paragraph 0073);

an outlet channel in fluid communication with the reaction chamber (Figure 1 and paragraph 0006, wherein the outlet channel is defined as the region of the flow cell downstream from the region having the immobilized primer complex; paragraph 0074);

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a first Raman detection unit operably coupled to the inlet channel (e.g., an optical detection device for detecting signals from the first illumination zone [paragraph 0069] wherein the first illumination zone is upstream of the immobilized complex; paragraph 0006); and

a second Raman detection unit operably coupled to the outlet channel (e.g., an optical detection device for detecting signals from the second illumination zone [paragraph 0070] wherein the second illumination zone is downstream of the immobilized complex; paragraph 0006).

Regarding claim 19, Davis teaches the apparatus of claim 18, wherein each Raman detection unit is capable of detecting at least one nucleotide at the single molecule level (e.g., the devices detects the optical properties of single molecules paragraph 0035).

Regarding claim 20, Davis teaches the apparatus of claim 18. The courts have held that “while features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function.” *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997). In addition, “[A]pparatus claims cover what a device *is*, not what a device *does*.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (emphasis in original). Therefore, the various uses recited in claim 20 (e.g., measuring concentration of nucleotides) fail to define additional structural elements to the device of claim 18. Because Davis teaches the structural elements of claim 18, Davis also anticipates claim 20. See MPEP § 2114.

2. Claims 18-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Shipwash (U.S. Patent Application Publication No. US 2002/0058273 A1, published 16 May 2002).

Regarding claim 18, Shipwash teaches an apparatus (e.g., an integrated microsystem using Raman spectroscopy; paragraph 0174) comprising:

a reaction chamber containing a single template nucleic acid molecule attached to an immobilization surface (paragraph 0043);

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an inlet channel in fluid communication with the reaction chamber (e.g., Figure 22, wherein the inlet channel comprises the channel having the digestion chamber; paragraphs 0482-0484);

an outlet channel in fluid communication with the reaction chamber (Figure 22, wherein the outlet channel is end of one of the reaction channels; paragraphs 0482-0484);

a first Raman detection unit operably coupled to the inlet channel (e.g., an optical detector is integrated onto the digestion chamber [paragraph 0484] and Raman Spectroscopy is used; paragraph 0174); and

a second Raman detection unit operably coupled to the channel (Figure 22, wherein the detector is a spectrophotometer [paragraph 0224] and Raman Spectroscopy is used; paragraph 0174).

Regarding claim 19, Shipwash teaches the apparatus of claim 18, wherein each Raman detection unit is capable of detecting at least one nucleotide at the single molecule level (e.g., the system employs detection is at the single molecule level; paragraph 0168).

Regarding claim 20, Shipwash teaches the apparatus of claim 18, wherein the concentrations of nucleotides are measured by Raman spectroscopy as they flow through the inlet channel and the outlet channel (e.g., the system detects concentration [paragraph 0170] and uses Raman spectroscopy; paragraph 0174). In addition, as stated above, the courts have held that “while features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function.” *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997). Because Shipwash teach the structural elements of claim 18, Shipwash also anticipates claim 20.

Regarding claim 21, Shipwash teaches the apparatus of claim 18 further comprising metal nanoparticles in the inlet channel and outlet channel (e.g., nucleic acids are on particles are in channels; paragraph 0043).

Regarding claim 22, Shipwash teaches the apparatus of claim 18, wherein the inlet channel and outlet channel diameter is between about 100 and about 200 micrometers in diameter (paragraph 0210).

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2. Claims 18 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shipwash (U.S. Patent Application Publication No. US 2002/0058273 A1, published 16 May 2002) in view of Anderson et al (U.S. Patent No. 6,168,948 B1, issued 2 January 2001).

Regarding claim 18, Shipwash teaches an apparatus (e.g., an integrated microsystem using Raman spectroscopy; paragraph 0174) comprising:

a reaction chamber containing a single template nucleic acid molecule attached to an immobilization surface (paragraph 0043);

an inlet channel in fluid communication with the reaction chamber (e.g., Figure 22, wherein the inlet channel comprises the channel having the digestion chamber; paragraphs 0482-0484);

an outlet channel in fluid communication with the reaction chamber (Figure 22, wherein the outlet channel is end of one of the reaction channels; paragraphs 0482-0484);

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a first Raman detection unit operably coupled to the inlet channel (e.g., an optical detector is integrated onto the digestion chamber [paragraph 0484] and Raman Spectroscopy is used; paragraph 0174); and

a second Raman detection unit operably coupled to the channel (Figure 22, wherein the detector is a spectrophotometer [paragraph 0224] and Raman Spectroscopy is used; paragraph 0174).

While Shipwash also teaches a device further comprising a mesh (e.g., filter and grids on the device; paragraphs 0167 and 0270), Shipwash is silent with respect to the materials used for the mesh.

However, Anderson et al teach a miniaturized integrated nucleic acid diagnostic device comprising nucleic acid binding sites (Abstract) and a platinum screen with the added advantage that the platinum screen allows reproducible electrochemical functions (column 43, lines 7-12).

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was claimed to have modified the apparatus of Shipwash with the platinum screen (e.g., mesh) of Anderson et al with a reasonable expectation of success. The ordinary artisan would have been motivated to make such a modification because the modification would have resulted in allowing reproducible electrochemical functions as explicitly taught by Anderson et al (column 43, lines 7-12).

Response to Arguments

Applicant's arguments filed 14 June 2006 (i.e., "the Remarks") have been fully considered but they are not persuasive for the reason(s) listed below.

1. Applicant's arguments on pages 8-9 of the Remarks with respect to the rejection of claim 18-23 under 35 U.S.C. 102(e) as being anticipated by Su et al have been considered but are moot in view of the withdrawal of the rejections.
2. Applicant argues on pages 8-9 of the Remarks that Davis et al teach neither the instantly claimed inlet and outlet channels, not the duplicate Raman detection units that are operably coupled to the inlet and outlet channels respectively.

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However, Davis et al do teach an inlet channel in fluid communication with the reaction chamber (Figure 1 and paragraph 0006, wherein the inlet channel is defined as the region of the flow cell upstream from the region having the immobilized primer complex; paragraph 0073); an outlet channel in fluid communication with the reaction chamber (Figure 1 and paragraph 0006, wherein the outlet channel is defined as the region of the flow cell downstream from the region having the immobilized primer complex; paragraph 0074); a first Raman detection unit operably coupled to the inlet channel (e.g., an optical detection device for detecting signals from the first illumination zone [paragraph 0069] wherein the first illumination zone is upstream of the immobilized complex; paragraph 0006); and a second Raman detection unit operably coupled to the outlet channel (e.g., an optical detection device for detecting signals from the second illumination zone [paragraph 0070] wherein the second illumination zone is downstream of the immobilized complex; paragraph 0006). Davis et al therefore anticipate all of the limitations of independent claim 18.

3. Applicant argues on pages 8-9 of the Remarks that Shipwash teaches neither the instantly claimed inlet and outlet channels, nor the duplicate Raman detection units that are operably coupled to the respective inlet and outlet channels.

However, Shipwash does teach an inlet channel in fluid communication with the reaction chamber (e.g., Figure 22, wherein the inlet channel comprises the channel having the digestion chamber; paragraphs 0482-0484); an outlet channel in fluid communication with the reaction chamber (Figure 22, wherein the outlet channel is end of one of the reaction channels; paragraphs 0482-0484); a first Raman detection unit operably coupled to the inlet channel (e.g., an optical detector is integrated onto the digestion chamber [paragraph 0484] and Raman Spectroscopy is used; paragraph 0174); and a second Raman detection unit operably coupled to the channel (Figure 22, wherein the detector is a spectrophotometer [paragraph 0224] and Raman Spectroscopy is used; paragraph 0174). Shipwash therefore anticipates all of the limitations of independent claim 18.

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4. The remaining arguments on pages 8-9 of the Remarks regarding dependent claims 19-23 rely on arguments set forth to address the rejections of independent claim 18 under 35 USC 102(b). Since the arguments regarding independent claim 18 were not persuasive, the rejections of dependent claims 19-23 are maintained.

Conclusion


1. No claim is allowed.
2. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
3. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.
4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert T. Crow whose telephone number is (571) 272-1113. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Robert T. Crow
Examiner
Art Unit 1634



JULIET C. SWITZER
PRIMARY EXAMINER